

[Revised as of October 1, 2003]

TITLE 45 Public Welfare and Human Services

PART 160 General Administrative Requirements

Subpart A--General Provisions

Sec. 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104-191, and section 264 of Public Law 104-191.

Sec. 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

Sec. 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in Sec. 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in Sec. 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such

organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of health plan in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of health plan in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) Health plan excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of \$5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

- (9) First report of injury.
- (10) Health claims attachments.
- (11) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

Sec. 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

Subpart B--Preemption of State Law

Sec. 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191.

Sec. 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

- (1) A covered entity would find it impossible to comply with both the State and federal requirements; or
- (2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104-191, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

- (1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:
 - (i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or
 - (ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

Sec. 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

- (a) A determination is made by the Secretary under Sec. 160.204 that the provision of State law:
 - (1) Is necessary:
 - (i) To prevent fraud and abuse related to the provision of or payment for health care;
 - (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
 - (iii) For State reporting on health care delivery or costs; or
 - (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or
 - (2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.
- (b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.
- (c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.
- (d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

Sec. 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under Sec. 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

- (1) The State law for which the exception is requested;
- (2) The particular standard, requirement, or implementation specification for which the exception is requested;
- (3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;
- (4) How health care providers, health plans, and other entities would be affected by the exception;
- (5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at Sec. 160.203(a); and
- (6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at Sec. 160.203(a) has been met.

Sec. 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

- (a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or
- (b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C--Compliance and Enforcement

Sec. 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with and the enforcement of the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

Sec. 160.302 Definitions.

As used in this subpart, terms defined in Sec. 164.501 of this subchapter have the same meanings given to them in that section.

Sec. 160.304 Principles for achieving compliance.

(a) Cooperation. The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) Assistance. The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

Sec. 160.306 Complaints to the Secretary.

(a) Right to file a complaint. A person who believes a covered entity is not complying with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter may file a complaint with the Secretary.

(b) Requirements for filing complaints. Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the Federal Register.

(c) Investigation. The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.

Sec. 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

Sec. 160.310 Responsibilities of covered entities.

(a) Provide records and compliance reports. A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) Cooperate with complaint investigations and compliance reviews. A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements of this part 160 and the standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(c) Permit access to information. (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter. If the Secretary

determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

Sec. 160.312 Secretarial action regarding complaints and compliance reviews.

(a) Resolution where noncompliance is indicated. (1) If an investigation pursuant to Sec. 160.306 or a compliance review pursuant to Sec. 160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) Resolution when no violation is found. If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

Subpart E--Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings

Sec. 160.500 Applicability.

This subpart applies to investigations conducted, penalties imposed, hearings conducted, and subpoenas issued, under the authority of 42 U.S.C. 1320d-5, relating to the imposition of civil money penalties.

Sec. 160.502 Definitions.

For the purposes of this subpart:

ALJ means Administrative Law Judge.

Entity means a legal person.

Penalty means the amount calculated under 42 U.S.C. 1320d-5, as determined in accordance with this part, and includes the plural of that term.

Person means a natural or legal person.

Respondent means the person upon whom the Secretary has imposed, or proposes to impose, a penalty.

Sec. 160.504 Investigational subpoenas and inquiries.

(a) The provisions of this paragraph govern subpoenas issued by the Secretary in accordance with 42 U.S.C. 405(d) and (e), 1320a-7a(j), and 1320d-5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation pursuant to this part.

(1) A subpoena issued under this paragraph must--

(i) State the name of the person to whom the subpoena is addressed;

- (ii) State the statutory authority for the subpoena;
- (iii) Indicate the date, time, and place that the testimony will take place;
- (iv) Include a reasonably specific description of any documents or items required to be produced; and
- (v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the named entity must designate one or more natural persons who will testify on its behalf, and must state as to each person so designated that person's name and address and the matters on which he or she will testify. The person so designated must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by--

- (i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

- (ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the District Court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

- (b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary.

- (1) Testimony at investigational inquiries will be taken under oath or affirmation.

- (2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

- (3) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

Sec. 160.506 Basis for penalty.

The Secretary shall impose a penalty on a person who is a covered entity and who the Secretary determines in accordance with this subpart has violated a provision of--

- (a) 42 U.S.C. 1320d-1320d-8, as amended;

- (b) Section 264 of Pub. L. 104-191 (42 U.S.C. 1320d-2(note)); or (c) Parts 160, 162 or 164 of this subchapter.

Sec. 160.508 Amount of penalty.

The penalty imposed under **Sec. 160.506** must be in accordance with 42 U.S.C. 1320d-5 and the applicable provisions of this part.

Sec. 160.510 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

Sec. 160.512 [Reserved]

Sec. 160.514 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include--

- (1) Reference to the statutory basis for the penalty;
- (2) A description of the findings of fact regarding the act(s) or omission(s) with respect to which the penalty is proposed;
- (3) The reason(s) why the act(s) or omission(s) subject(s) the respondent to a penalty;
- (4) The amount of the proposed penalty;
- (5) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty without the right to a hearing under Sec. 160.554 or a right of appeal under Sec. 160.568, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request therefor in accordance with Sec. 160.526 of this subpart.

Sec. 160.516 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by Sec. 160.526, the Secretary must impose the proposed penalty or any less severe penalty permitted by 42 U.S.C. 1320d-5. The Secretary must notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty. The respondent has no right to appeal under Sec. 160.568 with respect to a penalty with respect to which the respondent has not timely requested a hearing.

Sec. 160.518 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty must be collected by the Secretary.

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under 42 U.S.C. 1320a-7a(e) may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Sec. 160.520 [Reserved]

Sec. 160.522 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with Sec. 160.514 of this subpart, within 6 years from the date on which the latest act or omission that is the subject of the action occurred.

Sec. 160.524 [Reserved]

Sec. 160.526 Hearing before an ALJ.

(a) The respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of--

- (1) The respondent; and
- (2) The Secretary.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 60 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.

(d) The ALJ must dismiss a hearing request where--

- (1) The respondent's hearing request is not filed as required by paragraphs (b) and (c) of this section;
- (2) The respondent withdraws the request for a hearing;
- (3) The respondent abandons the request for a hearing; or
- (4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

Sec. 160.528 Rights of parties.

(a) Except as otherwise limited by this part, each party may--

- (1) Be accompanied, represented, and advised by an attorney;
- (2) Participate in any conference held by the ALJ;
- (3) Conduct discovery of documents as permitted by this subpart;
- (4) Agree to stipulations of fact or law that will be made part of the record;
- (5) Present evidence relevant to the issues at the hearing;
- (6) Present and cross-examine witnesses;
- (7) Present oral arguments at the hearing as permitted by the ALJ; and
- (8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

Sec. 160.530 Authority of the ALJ.

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may--

- (1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;
- (2) Continue or recess the hearing in whole or in part for a reasonable period of time;
- (3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
- (4) Administer oaths and affirmations;

- (5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;
 - (6) Rule on motions and other procedural matters;
 - (7) Regulate the scope and timing of documentary discovery as permitted by this subpart;
 - (8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;
 - (9) Examine witnesses;
 - (10) Receive, rule on, exclude, or limit evidence;
 - (11) Upon motion of a party, take official notice of facts;
 - (12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and
 - (13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.
- (c) The ALJ may not--
- (1) Find invalid or refuse to follow Federal statutes or regulations or delegations of authority by the Secretary;
 - (2) Enter an order in the nature of a directed verdict;
 - (3) Compel settlement negotiations; or
 - (4) Enjoin any act of the Secretary.

Sec. 160.532 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

Sec. 160.534 Prehearing conferences.

- (a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.
- (b) The ALJ may use prehearing conferences to discuss the following-
 - (1) Simplification of the issues;
 - (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
 - (3) Stipulations and admissions of fact or as to the contents and authenticity of documents;
 - (4) Whether the parties can agree to submission of the case on a stipulated record;
 - (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;
 - (6) Limitation of the number of witnesses;
 - (7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
 - (8) Discovery of documents as permitted by this subpart;
 - (9) The time and place for the hearing;
 - (10) The potential for the settlement of the case by the parties; and
 - (11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of privacy of individually identifiable health information that may be submitted into evidence, if appropriate.
- (c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

Sec. 160.536 Settlement.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

Sec. 160.538 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term "documents" includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought--

- (i) Is irrelevant;
- (ii) Is unduly costly or burdensome;
- (iii) Will unduly delay the proceeding; or
- (iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

Sec. 160.540 Exchange of witness lists, witness statements, and exhibits.

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with Sec. 160.556, at least 15 days before the hearing, unless the ALJ orders an earlier exchange.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief--

- (i) The testimony of any witness whose name does not appear on the witness list; and
- (ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party. If the ALJ finds

that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

Sec. 160.542 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. That motion must--

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

Sec. 160.544 Fees.

The party requesting a subpoena must pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage must accompany the subpoena when served, except that when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

Sec. 160.546 Form, filing, and service of papers.

(a) Forms. (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) Service. A party filing a document with the ALJ or the Secretary must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) Proof of service. A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

Sec. 160.548 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to requests for hearing under Sec. 160.526.

Sec. 160.550 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

Sec. 160.552 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include--

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

- (e) Dismissal of the action;
- (f) Entering a decision by default;
- (g) Ordering the party or attorney to pay the attorney's fees and other costs caused by the failure or misconduct; and
- (h) Refusing to consider any motion or other action that is not filed in a timely manner.

Sec. 160.554 The hearing.

- (a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.
- (b) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.
- (c) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with Sec. 160.540.

Sec. 160.556 Witnesses.

- (a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.
- (b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. Any such written statement must be provided to all other parties along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in Sec. 160.540.
The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony.
- (c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:
 - (1) Make the interrogation and presentation effective for the ascertainment of the truth;
 - (2) Avoid repetition or needless consumption of time; and
 - (3) Protect witnesses from harassment or undue embarrassment.
- (d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.
- (e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This provision does not authorize the exclusion of--
 - (1) A party who is a natural person;
 - (2) In the case of a party that is an entity, the officer or employee of the party appearing for the entity pro se or designated as the party's representative; or
 - (3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

Sec. 160.558 Evidence.

- (a) The ALJ must determine the admissibility of evidence.
- (b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.
- (c) The ALJ must exclude irrelevant or immaterial evidence.
- (d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

- (e) Although relevant, evidence may be excluded if it is privileged under Federal law.
- (f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.
- (g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination sent in accordance with Sec. 160.514.
- (h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.
- (i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

Sec. 160.560 The record.

- (a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.
- (b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.
- (c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.
- (d) For good cause, the ALJ may order appropriate redactions made to the record.

Sec. 160.562 Post hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

Sec. 160.564 ALJ decision.

- (a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.
- (b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.
- (c) The ALJ must issue the decision to both parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.
- (d) The ALJ's decision is the final decision of the Secretary.

Sec. 160.566 [Reserved]

Sec. 160.568 Judicial review.

Judicial review of a penalty that has become final is authorized by 42 U.S.C. 1320a-7a(e).

Sec. 160.570 Stay of ALJ decision.

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of the request automatically stays the effective date of the penalty until such time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.

Sec. 160.572 [Reserved]